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UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA
SAN JOSE DIVISION

UNITED STATES OF AMERICA,)	Case No. CR-18-00258-EJD
)	
Plaintiff,)	MS. HOLMES' REPLY IN SUPPORT OF
)	MOTION TO EXCLUDE EXPERT
v.)	TESTIMONY OR, IN THE ALTERNATIVE,
)	COMPEL ADEQUATE RULE 16 DISCLOSURE
ELIZABETH HOLMES and)	
RAMESH "SUNNY" BALWANI,)	Date: July 20, 2020
)	Time: 10:00 a.m.
Defendants.)	CTRM: 4, 5th Floor
)	
)	Hon. Edward J. Davila
)	
)	

MS. HOLMES' REPLY IN SUPPORT OF MOTION TO EXCLUDE EXPERT TESTIMONY
OR, IN THE ALTERNATIVE, COMPEL ADEQUATE RULE 16 DISCLOSURE
CR-18-00258 EJD

TABLE OF CONTENTS

INTRODUCTION	1
ARGUMENT	2
I. The Rule 16 Standards Apply to These Witnesses.	2
A. Rule 16 Applies to All Expert Testimony.....	2
B. The Government Must Provide More Than “Generic” Descriptions.	5
II. The Government’s Disclosure Remains Inadequate.....	9
A. The Government Failed To Provide a Summary for Its Experts’ Opinions and the Bases and Reasons for Those Opinions.....	9
B. The Government’s Discovery Does Not Cure Its Insufficient Disclosure	9
CONCLUSION.....	11

TABLE OF AUTHORITIES

CASES

<i>Fresenius Med. Care Holdings v. Baxter Int’l, Inc.</i> , 2006 WL 1330002 (N.D. Cal. May 15, 2006)	4
<i>Goodman v. Staples the Office Superstore, LLC</i> , 644 F.3d 817 (9th Cir. 2011)	4
<i>United States v. Cerna</i> , 2010 WL 2347406 (N.D. Cal. June 8, 2010).....	2, 7, 8, 9
<i>United States v. Figueroa-Lopez</i> , 125 F.3d 1241 (9th Cir. 1997)	<i>passim</i>
<i>United States v. Valdez</i> , 2019 WL 539074 (N.D. Cal. Feb. 11, 2019)	10
<i>Vollrath Co. v. Sammi Corp.</i> , 9 F.3d 1455 (9th Cir. 1993).....	7
<i>Walker v. Contra Costa Cty.</i> , 2006 WL 3371438 (N.D. Cal. Nov. 21, 2006).....	4

RULES

Fed. R. Crim. P. 16	2, 8
Fed. R. Evid. 701	3, 4, 5
Fed. R. Evid. 702	<i>passim</i>

INTRODUCTION

Rather than engage with Ms. Holmes' arguments about the infirmities of its Rule 16 disclosure, the government argues for a lesser standard for its "fact" expert witnesses. Gov't Opp'n to Mot. To Exclude Expert Testimony ("Gov't Opp'n), ECF No.441, at 8-10. According to the government, because the at-issue witnesses are percipient witnesses and "are not primarily expert witnesses," its paltry Rule 16 disclosures are sufficient. The Court must reject this argument.

As an initial matter, the government's disclosure makes clear that these witnesses will be proffering expert opinions that go to a core issue in this case: the government's allegation, underlying the alleged patient conspiracy, that Theranos tests were "inaccurate." *Id.* at 1. These are not merely percipient witnesses. The witnesses will use their specialized medical knowledge to reach opinions about complex medical tests. Notably, the government plans to elicit testimony and opinions from these witnesses about specific Theranos tests for which the government's own retained expert was unable to draw conclusions as to accuracy and reliability. The government intends to use their opinions to do what it cannot do with its retained expert's testimony: to urge the jury to conclude that specific Theranos tests were inaccurate and unreliable. As a matter of due process, Ms. Holmes is entitled to adequate disclosure to challenge those core expert assertions, and to ensure that she can vindicate her constitutional rights when confronting these witnesses.

In any event, the Ninth Circuit has rejected the very argument the government presents here. There is no "percipient witness" or "minimal expert testimony" exception to Rule 16. For each witness who provides expert testimony, the government must provide a summary of that witness's opinion and the bases and reasons for the opinion. As the Ninth Circuit has held, "[t]he mere percipience of a witness to the facts on which he wishes to tender an opinion does not trump Rule 702." *United States v. Figueroa-Lopez*, 125 F.3d 1241, 1246 (9th Cir. 1997).

The government's opposition leaves many of Ms. Holmes' substantive points unanswered. Ms. Holmes does not know the content of some of the experts' opinions; she does not know the bases and reasons for several of the experts' opinions; and she does not have the basic information required to test

the reliability or credibility of these experts through “focused cross-examination” or to frame a *Daubert* motion. *Id.*; see also *United States v. Cerna*, 2010 WL 2347406, at *1 (N.D. Cal. June 8, 2010) (the summary of the “bases and reasons must be sufficient to allow counsel to frame a *Daubert* motion”). And the minimal discovery produced by the government does not provide this missing information. The Court should exclude these witnesses from providing expert testimony, or, in the alternative, compel adequate disclosures.

ARGUMENT

Federal Rule of Criminal Procedure 16 requires the government to provide, for any witness who may offer expert testimony, a description of the witness’s opinions and the bases and reasons for the opinions. The Rule “‘is intended to minimize surprise that often results from unexpected testimony, reduce the need for continuances, and to provide the opponent with a fair opportunity to test the merit of the expert’s testimony through focused cross-examination.’” *Figueroa-Lopez*, 125 F.3d at 1246 (quoting Fed. R. Crim. P. 16 Advisory Committee Note). The government fails to provide this basic information for many of its witnesses.

I. The Rule 16 Standards Apply to These Witnesses.

The government primarily urges this Court to apply a lower standard than articulated under Rule 16. Gov’t Opp’n at 8-10. It argues that for “expert witnesses[] who will be presenting only ‘generic’ expert testimony, and who will primarily be testifying as percipient witnesses,” “all that Rule 16 requires” is limited expert notice. *Id.* at 10. The Court should reject the government’s invitation to create such a standard here.

A. Rule 16 Applies to All Expert Testimony.

Rule 16 does not distinguish between percipient and retained expert witnesses. The government cannot skirt Rule 16 by calling these experts percipient witnesses who will provide limited expert testimony. *Id.* at 8-10. Such a tactic is foreclosed by both the Federal Rules and Ninth Circuit precedent. The Advisory Committee Note to Federal Rule of Evidence 701 “makes clear that *any part of a witness’ testimony* that is based upon scientific, technical, or other specialized knowledge . . . is

governed by the standards of Rule 702 and the corresponding disclosure requirements of the Civil and Criminal Rules.” Fed. R. Evid. 701 Advisory Committee Note to 2000 Amendment (emphasis added). The Note explicitly states that “[b]y channeling testimony that is actually expert testimony to Rule 702, the amendment also ensures that a party will not *evade the expert witness disclosure requirements* set forth in Fed. R. Civ. P. 26 and Fed. R. Crim. P. 16 by *simply calling an expert witness in the guise of a layperson*.” *Id.* (emphasis added). Any witness who offers testimony based on scientific, technical, or specialized knowledge is subject to Rule 702, and Rule 16’s disclosure requirement is tied to Rule 702. Rule 16 applies to any witness who will offer testimony subject to Rule 702.

The Ninth Circuit has reaffirmed this point. In *Figueroa-Lopez*, the court rejected the very argument that the government makes here—*i.e.*, that lay witnesses’ opinions are based on their percipient knowledge and therefore are not subject to the same requirements as expert witnesses. 125 F.3d at 1246. The government argued that the testimony of its witnesses, DEA agents, about the defendant’s actions was the proper subject of lay opinion testimony because the testimony was based on the agents’ direct observations of the defendant. *Id.* at 1243. As a result, the government argued, the witnesses were “percipient witnesses” not subject to the requirements of Rule 702. *Id.*

The Ninth Circuit rejected this position, observing that the “Government’s argument simply blurs the distinction between Federal Rules of Evidence 701 and 702.” *Id.* Rule 701 limits opinions to those “rationally based on the perception of the witness,” and Rule 702, “on the other hand, governs admission of expert opinion testimony concerning ‘*specialized knowledge*.’” *Id.* (emphasis in original). Critically, the court explained that “the Government’s argument subverts the requirements of Federal Rule of Criminal Procedure 16(a)(1)(E). . . [which] requires the Government to ‘disclose to the defendant a written summary of [expert] testimony the government intends to use . . . during its case in chief.’” *Id.* That is exactly the circumstance that confronts Ms. Holmes here. The government is attempting to use the label “percipient witness” to avoid its disclosure obligations under Rule 16.

As the court explained, regardless of whether the testimony is based on the witness’s perception, if the testimony requires the witness to draw on specialized knowledge, it falls under Rule 702. *Id.*; *see*

1 *also Fresenius Med. Care Holdings, Inc. v. Baxter Int'l, Inc.*, 2006 WL 1330002, at *3 (N.D. Cal. May
2 15, 2006) (“Lay opinion testimony is ‘not to provide specialized explanations or interpretations that an
3 untrained layman could not make if perceiving the same acts or events.’”(citation omitted)).

4 Accordingly, the court held that “[t]he mere percipience of a witness to the facts on which he wishes to
5 tender an opinion does not trump Rule 702.” *Figueroa-Lopez*, 125 F.3d at 1246. “A holding to the
6 contrary would encourage the Government to offer all kinds of specialized opinions without pausing
7 first properly to establish the required qualifications of their witnesses.” *Id.*

8 *Goodman v. Staples the Office Superstore, LLC*, 644 F.3d 817 (9th Cir. 2011), which the
9 government cites for the proposition that “[t]reating physicians ‘are not specially hired to provide expert
10 testimony’” and therefore no expert report is required, Gov’t Opp’n at 8, is not to the contrary. As an
11 initial matter, *Goodman* construed the civil expert disclosure requirement of Rule 26 of the Federal
12 Rules of Civil Procedure. 644 F.3d at 819. The government provides no authority for the proposition
13 that criminal cases—which concern heightened constitutional protections for the defendant—should
14 borrow standards from the rules of civil procedure when it comes to expert witnesses. But, even if the
15 civil standards were relevant, *Goodman* does not help the government. *Goodman* does not hold that
16 “treating physicians are exempted from expert notice” provisions in all cases. Gov’t Opp’n at 8. Just
17 the opposite: *Goodman* explicitly states that when treating physicians testifies on matters outside the
18 treatment of their patients they must provide a report. 644 F.3d at 819-20 (“We hold today that when a
19 treating physician morphs into a witness hired to render expert opinions that go beyond the usual scope
20 of a treating doctor’s testimony, the proponent of the testimony must comply with Rule 26(a)(2).”).
21 When a treating physician’s testimony extends beyond what he “actually observed and what treatment
22 he provided,” a disclosure is required. *Walker v. Contra Costa Cty.*, 2006 WL 3371438, at *9 (N.D.
23 Cal. Nov. 21, 2006). For the reasons set forth below, the government’s experts’ testimony goes far
24 beyond what they observed and what treatment they provided.

25 Relatedly, the government argues that its experts’ observations about other laboratories are not
26 opinions at all but merely their own personal observations and therefore fall under Rule 701. Gov’t

Opp'n at 8-9. However, the government cannot disguise these expert opinions as lay testimony simply because an expert witness is also a percipient witness. These "observations" are unquestionably based on specialized knowledge. If the government intends to elicit testimony about the quality, types, and frequency of the errors in different laboratories, specialized knowledge is needed for that opinion to be admissible. Ms. Embry, for example, opined in her FBI interview that in "approximately 20 years" any errors she had with Sonora Quest and Lab Corp "were administrative errors, not clinical ones." Gov't Opp'n, Ex. 6 at 1. That is a specialized opinion: how did she deduce that Sonora Quest's errors were merely "administrative" errors whereas Theranos' alleged errors were "clinical" ones? What is the basis for that distinction? Because of the government's inadequate disclosure, Ms. Holmes can only guess at the answer to that question. As in *Figueroa-Lopez*, the government's argument "simply blurs the distinction between Federal Rules of Evidence 701 and 702." 125 F.3d at 1246; *see also id.* (stating that "judges who have heard [specialized] testimony many times . . . must not forget that [their] familiarity with it does not bring it within Rule 701, especially given the purpose of Rule 16"). The government elected to disclose these observations as part of its expert disclosure. Ms. Holmes is entitled to know the bases and reasons for these opinions so she can fairly challenge them at trial.

B. The Government Must Provide More Than "Generic" Descriptions.

The government similarly characterizes its experts' testimony as "generic" and, on that basis, argues that Rule 16 requires only a "generic description of the likely witness and that witness's qualifications." Gov't Opp'n at 9 (citing Fed. R. Crim. P. 16, Advisory Committee Notes to 1993 Amendment). According to the government, "[n]othing in these witnesses' expected testimony will present novel or controversial opinions that might be the subject of a *Daubert* hearing," and therefore a generic description suffices. *Id.* That is wishful thinking: these witnesses are presenting substantive opinions on complex medical questions, and their opinions present serious *Daubert* questions. At the very minimum, the government needs to provide basic information such as whether the witnesses' opinions are based on known objective facts concerning specific patients and why those facts led them to believe that the Theranos tests were inaccurate.

1 There is nothing “generic” or routine about the testimony of these witnesses. The following
 2 examples illustrate how the government intends to elicit opinion testimony that goes well beyond the
 3 treatment of a specific patient and is not simply “generic”:

- 4 • The government plans to elicit testimony from Dr. Linnerson about “problematic hCG test
 5 results from Theranos,” although it has only identified one patient who received a
 6 “problematic” result. *See* Gov’t Opp’n at 2. It also plans to elicit testimony about “the
 7 actions he and his clinic took” in setting up “a small study” comparing his clinic’s patients
 8 hCG results with other laboratories and that the results of the study “failed to restore
 9 confidence” in Theranos’ tests. *Id.* at 2-3. If anything is subject to Rule 702 and *Daubert*,
 10 testimony about a medical “study” and the interpretation of the study results surely is.
- 11 • The government also plans to elicit testimony from Dr. Zachman about this same study and
 12 how she “worked with Dr. Linnerman [sic] and others in the clinic” to conduct the study. *Id.*
 13 at 3.
- 14 • Dr. Szmuc worked in the same practice as Drs. Linnerson and Zachman, and the government
 15 will attempt to elicit opinions concerning the hypothetical ramifications of inaccurate tests
 16 such as ordering “surgical or pharmaceutical intervention.” *Id.* at 4.
- 17 • The government plans to elicit from Ms. Embry that Theranos tests could have hypothetically
 18 caused patient harm if she adjusted a patient’s medication based on a Theranos test. Gov’t
 19 Opp’n, Ex. 6 at 3. It also intends to ask her to opine that any unexpected Theranos results
 20 were clinical errors, but that unexpected Sonora Quest results were “administrative errors.”
 21 *Id.* at 1. No basis for that opinion has been described.
- 22 • Dr. Page will testify that “he did not understand how Theranos could not have known they
 23 had a problem with A1Cs for months.” Gov’t Opp’n at 8. This opinion, if offered,
 24 necessarily draws on his specialized knowledge. This testimony does not merely describe his
 25 percipient observations; it opines on what Theranos should have known based on those
 26

1 observations. And this opinion presents significant questions under *Daubert*, because it is
 2 unclear that Dr. Page has a sufficient basis to offer such an opinion.

- 3 • The government disclosed that Dr. Asin will opine that a Theranos test result for an HIV test
 4 that was reactive for certain antibodies and not reactive for others “did not make sense.” *Id.*
 5 at 6-7. This is an expert opinion that draws on his specialized knowledge. And depending
 6 on the principles he applied to reach this opinion, it could well be subject to challenge under
 7 *Daubert*. The government also disclosed that Dr. Asin will opine on a hypothetical invasive
 8 procedure that a doctor may order to recheck a PSA test, though he identifies no patient for
 9 whom such a procedure was performed. *Id.* at 7.

10 Contrary to the government’s argument, these disclosures indicate that the government intends to elicit
 11 medical expert testimony that goes well beyond “merely . . . explaining what the values for [Theranos]
 12 tests mean.” *Id.* at 9.

13 The government’s assertion that the witnesses’ expected testimony will not present controversial
 14 opinions that might be the subject for a *Daubert* hearing reflects a fundamental misunderstanding of the
 15 standards articulated in *Daubert*. What are the bases for the witnesses’ opinions? Have they relied on
 16 sufficiently reliable data in forming their opinions? What is that data? To the extent their opinions
 17 about the accuracy of Theranos tests rest on isolated patient anecdotes and not a reliable body of data or
 18 evidence, their opinions will present serious reliability problems. *See, e.g., Vollrath Co. v. Sammi*
 19 *Corp.*, 9 F.3d 1455, 1462 (9th Cir. 1993). Ms. Holmes cannot even begin to provide answers for those
 20 questions because of the government’s failure to provide a sufficiently detailed disclosure. *See Cerna*,
 21 2010 WL 2347406, at *1 (stating that the summary of the “bases and reasons must be sufficient to allow
 22 counsel to frame a *Daubert* motion”).

23 The experts’ opinions, moreover, go to a core issue in this case: the accuracy and reliability of
 24 Theranos tests. Critically, the government’s retained expert, Dr. Stephen Master, has offered only
 25 limited opinions about Theranos tests. In his expert report, Dr. Master fails to offer an actual opinion
 26 about whether Theranos’ hCG, HIV, A1C or calcium test were accurate and reliable; his report indicates

that he lacks sufficient data to reach an opinion on those subjects. *See* Declaration of Amy Mason Saharia (“Saharia Decl.”), Ex. A. at 12 (Expert Disclosure of Dr. Stephen Master) (explaining only that he had “questions” about these tests). The government apparently intends to use these witnesses to fill the holes in those opinions. In fact, the disclosed experts cover all the tests for which Dr. Master was unable to opine: hCG (Linnerson, Zachman, Szmuc), A1C (Page), HIV (Asin), and calcium (Asin). *See* Gov’t Opp’n at 2-8. Their testimony is quintessential expert opinion testimony, and it goes to a core issue in this case. The government must be required to comply with Rule 16.

Finally, the government ignores that, even if it were permitted to provide a “generic” description of its witnesses’ opinions, it must *also* provide the bases and reasons for those opinions. Rule 16 provides three distinct requirements for an expert summary: (1) “the witness’s opinions;” (2) “the bases and reasons for those opinions;” and (3) “the witness’s qualifications.” Fed. R. Crim. P. 16(a)(1)(G). The Advisory Committee Notes to the 1993 Amendment—on which the government relies—allow for a “generic description” in some instances of the “summary of the expected testimony.” However, for the “most important” requirement—the “summary of the bases of the expert’s opinion”—the Notes do not allow the government to provide a generic description:

Without regard to whether a party would be entitled to the underlying bases for expert testimony under other provisions of Rule 16, the amendment requires a summary of the bases relied upon by the expert. That should cover not only written and oral reports, tests, reports, and investigations, but any information that might be recognized as a legitimate basis for an opinion under Federal Rule of Evidence 703.

Fed. R. Crim. P. 16 Advisory Committee Notes to 1993 Amendment.

United States v. Cerna, the case on which the government relies for its “generic” argument, proves the point. It states that “where a witness is so ‘generic’ and routine (such as a DEA laboratory chemist) that the testimony will be largely predictable, a shorthand summary of the witness’s *qualifications and testimony* may be adequate.” 2010 WL 2347406, at *1 (emphasis added). However, the “summary of bases relied upon by the expert ‘should cover . . . any information that might be recognized as a legitimate basis for an opinion under Federal Rule of Evidence 703.’” *Id.* (citing Fed. R.

Crim. P. 16 Advisory Committee Notes to 1993 Amendment). The government cannot escape this requirement by labeling its expert witnesses' testimony as "generic."

II. The Government's Disclosure Remains Inadequate.

A. The Government Failed To Provide a Summary for Its Experts' Opinions and the Bases and Reasons for Those Opinions.

For the reasons set forth in Ms. Holmes' motion, the government's disclosure is, and remains, inadequate. *See* Def.'s Mot. To Exclude Expert Testimony ("Def.'s Mot."), ECF No. 435. *First*, for two witnesses, Dr. Page and Dr. Asin, it does not provide an opinion at all—it just states that the witnesses will testify about certain tests. *Id.* at 3-4. *Second*, the government failed to provide the bases and reasons for many of the opinions that it does identify. *Id.* at 3-7. And, for the reasons set forth above, these opinions go far beyond percipient testimony of a treating physician.

Rule 16 demands more. The government has not provided and is required to provide the following:

1. An explicit opinion for each Theranos test referenced in each witness's summary;
2. The specific patients and test results on which the witnesses are basing their opinions (or it should clarify that there are no specific patients);
3. The bases of and reasons for their conclusions that such test results were inaccurate or unreliable; and
4. The bases of and reasons for their opinions regarding the accuracy of other laboratories' tests.

This should not be a difficult task. If the government is going to proffer these witnesses to offer opinions about a central allegation—that Theranos tests were inaccurate and unreliable—as its opposition and disclosure indicate it will, the Constitution and Rule 16 entitle Ms. Holmes to this bare minimum of information.

B. The Government's Discovery Does Not Cure Its Insufficient Disclosure.

The government tries to paper over the obvious gaps in its disclosure by pointing generally to discovery in this case. *See* Gov't Opp'n at 9. Although discovery may provide context for the summary of the witnesses' testimony, "the production of additional documents cannot satisfy a rule that requires a

1 “summary” that “describe[s] . . . the *bases and reasons* for [the expert witness's] opinions.” *United*
 2 *States v. Valdez*, 2019 WL 539074, at *3 (N.D. Cal. Feb. 11, 2019) (emphasis added). The government
 3 has not shown, and cannot show, that the discovery discloses the bases and reasons for the doctors’
 4 opinions, for several reasons:

5 1. The government’s one-paragraph defense of its disclosures says nothing about providing
 6 the bases and reasons for its witnesses’ opinions. The government refuses to confront this requirement
 7 and for that reason alone its arguments must fail.

8 2. The government seizes on its assertion that it has “provided all the relevant discovery in
 9 its custody and control relating to doctor witnesses, as well as their patients.” Gov’t Opp’n at 9. But
 10 this discovery is extremely limited. Across the seven experts, the collective interview memoranda name
 11 *four* total patients. A number of these experts did not name a single patient who formed the basis for
 12 their opinions. The government has produced a grand total of *two* interview memoranda for patients of
 13 these experts. And, in many cases, the government collected *no* or extremely limited documents from
 14 these experts. This limited amount of disclosure does not help Ms. Holmes figure out the basis and
 15 reasons for these experts’ opinions.

16 3. With respect to the two experts for which the government did not even disclose an
 17 opinion for certain tests (Dr. Page and Dr. Asin), the government points to its discovery production,
 18 including its FBI 302 interview memoranda. But Dr. Page’s and Dr. Asin’s disclosures do not fix this
 19 problem. Dr. Page’s 302 says nothing about what his opinion will be for complete blood count (CBC)
 20 tests. *Id.* at 7-8. For Dr. Asin, the government states that Dr. Asin “recalled” that Theranos diabetic
 21 tests did not “seem as accurate, and protein and calcium tests that seemed incorrect as well,” but that
 22 barebones assertion come nowhere close to complying with Rule 16. *Id.* at 7. It says nothing about why
 23 or how he reached that opinion.

24 4. The government complains that it does not have the ability to search for patients in
 25 Theranos’ database. *Id.* at 7 n.1.¹ But the government’s inability to substantiate its experts’ “opinions”

26 ¹ It bases this assertion on a statement made in a civil case about a civil litigant’s attempt to access the
 27 database. The government, which has highly sophisticated data recovery abilities, says nothing about its
 28 MS. HOLMES’ REPLY IN SUPPORT OF MOTION TO EXCLUDE EXPERT TESTIMONY
 OR, IN THE ALTERNATIVE, COMPEL ADEQUATE RULE 16 DISCLOSURE
 CR-18-00258 EJD

1 with data does not allow it to circumvent Rule 16 (or the *Daubert* standards for that matter). The
 2 government argues that it has to “piece together” test results from records patients may have kept or
 3 from records within doctors’ offices. *Id.* But, as just set forth, it has not consistently done so. If it had
 4 done so, it presumably would have identified actual patients in its disclosures. Equally importantly, if
 5 that is so, the same holds true for Ms. Holmes. Ms. Holmes cannot “piece together” the bases for these
 6 experts’ opinions without a complete and accurate disclosure, and the government should not be
 7 permitted to substitute vague opinions for the investigative work it needs to do to prove its case. Ms.
 8 Holmes needs to know which records and patients form the bases for these experts’ opinions, to avoid
 9 unfair surprise at trial and to enable her to serve Rule 17 subpoenas to access relevant evidence.

10 The government’s opposition and discovery resolve none of these problems. The Court should
 11 exclude the testimony of the government’s experts. In the alternative, the Court should order the
 12 government to provide an adequate disclosure.

13 CONCLUSION

14 For these reasons, this Court should grant Ms. Holmes’ motion.

15
 16 DATED: July 13, 2020

Respectfully submitted,

17 /s/ Amy Mason Saharia

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 27 own attempts, if any, to access the patient database.

MS. HOLMES’ REPLY IN SUPPORT OF MOTION TO EXCLUDE EXPERT TESTIMONY

28 OR, IN THE ALTERNATIVE, COMPEL ADEQUATE RULE 16 DISCLOSURE

CR-18-00258 EJD

CERTIFICATE OF SERVICE

I hereby certify that on July 13, 2020 a copy of this filing was delivered via ECF on all counsel of record.

/s/ Amy Mason Saharia
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